ASCELIA PHARMA

*Advancing Orphan Oncology*

# FULL-YEAR REPORT 2022

**January – December 2022**

## Orviglance phase 3 study, SPARKLE, expected to be completed in Q1 2023.

### SIGNIFICANT EVENTS IN Q4 2022

- New strong Orviglance data support successful SPARKLE completion with substantially fewer patients.
- Ascelia Pharma expands management team to prepare for commercialization.
- Presentation at the RSNA congress of results from Orviglance food effect study showing strong liver enhancement both with light meal and in fasting condition.
- 65 patients have completed SPARKLE at the end of 2022.

### SIGNIFICANT EVENTS AFTER THE PERIOD

- 71 patients have completed the SPARKLE study by January 27 2023.

*"The progress of the phase 3 clinical trial SPARKLE in the fourth quarter and early 2023 will guide us towards a successful 2023."*

### KEY RATIOS GROUP

| | Q4 (Oct-Dec) | | FY (Jan-Dec) | |
|---|---|---|---|---|
| | **2022** | 2021 | **2022** | 2021 |
| **OPERATING RESULT (SEKm)** | | | | |
| | **-52.2** | -39.2 | **-147.0** | -137.9 |
| **EARNINGS PER SHARE (SEK)** | | | | |
| | **-1.53** | -1.01 | **-3.77** | -3.82 |
| **CASH FLOW FROM OPERATIONS (SEKm)** | | | | |
| | **-28.7** | -32.2 | **-125.3** | -116.6 |
| **LIQUID ASSETS INCL. MARKETABLE SECURITIES (SEKm)** | | | | |
| | **149.6** | 261.6 | **149.6** | 261.6 |

# CEO COMMENTS

The fourth quarter of 2022 completed a very intense and productive year for Ascelia Pharma, with a particular focus on the important Phase 3 program with our investigational magnetic resonance imaging (MRI) contrast agent Orviglance®. In December, we presented an updated plan for the pivotal Phase 3 clinical SPARKLE study with Orviglance that will now be completed with 80 patients due to a significantly higher Orviglance effect than originally expected. Earlier in the year, we successfully completed the two other clinical studies which are part of our Phase 3 program for Orviglance – the Hepatic Impairment Study and the Food Effect Study. Our progress in the development of Orviglance in the fourth quarter sets us on course for a successful 2023.

**Orviglance Phase 3 program.** In the autumn, we had constructive dialogues with the American Food and Drug Administration (FDA) regarding the ongoing phase 3 study SPARKLE. Based on these discussions, we decided and announced in December that the study will be completed with significantly fewer patients than originally planned and the patient enrollment target has been reduced from up to 200 to 80 patients.

We highly value the constructive dialogue with the FDA and we are highly encouraged by the strong efficacy seen in the new statistical analysis of existing data.

By January 27, 2023, 71 patients had undergone the study, and we expect to complete SPARKLE patient enrollment by February/March 2023, with headline results by mid-2023.

In 2022, we also successfully completed two other clinical studies – the Hepatic Impairment Study and the Food Effect Study – that have run in parallel with SPARKLE. In September, we announced the final results of the Hepatic Impairment Study, confirming that Orviglance is well tolerated in patients with hepatic impairment. In May, the Food Effect study successfully concluded that Orviglance image enhancement is strong both in a fasting condition and with a light meal.

**Continued strong scientific interest in Orviglance.** Results from the Food Effect Study were presented as an oral presentation at the world's largest radiology conference, RSNA, November 27 – December 1 in Chicago. Earlier in the year, at the annual ESGAR conference in Lisbon, Portugal, we presented positive results from a study comparing Orviglance to a gadolinium-based contrast agent as well as with unenhanced MRI. Importantly, the evaluation was made using the same methodology and parameters as is being used in SPARKLE and hence has provided us with a data-driven approach for reducing the size of the SPARKLE study.

**Continued strong belief in Oncoral, which further strengthens our intellectual property rights.** Our strong belief in Oncoral remains unchanged based on the Notice of Allowance for a US patent for our novel oral chemotherapy treatment Oncoral which is in development,

**Expanded leadership team and management changes.** In October, the Ascelia Pharma leadership team was expanded to seven members who are responsible for all the important line functions in Ascelia Pharma. The expansion of our leadership team is an important step in our preparations to successfully transform Ascelia Pharma into a commercial stage company.

Our Chief Medical Officer (CMO) Carl Bjartmar decided to retire by the end of 2022. We thank him for his great contribution to Ascelia Pharma and its development and wish him all the best.

**Financial position.** Our progress requires access to liquidity. We have a solid balance sheet and closed the fourth quarter with 149.6 MSEK in cash, which will take us into Q4 2023. The liquidity position will primarily be used to finalize the ongoing Phase 3 program as well as preparing the Orviglance regulatory submission and pre-launch activities.

**Looking ahead.** The entire Ascelia Pharma team is excited to bring Orviglance forward towards a successful 2023, with completion of patient enrollment, headline results and preparations of regulatory submission and launch. I look forward to update you on our achievements as we bring Ascelia Pharma successfully forward.

**Magnus Corfitzen,** CEO

# ADVANCING ORPHAN ONCOLOGY

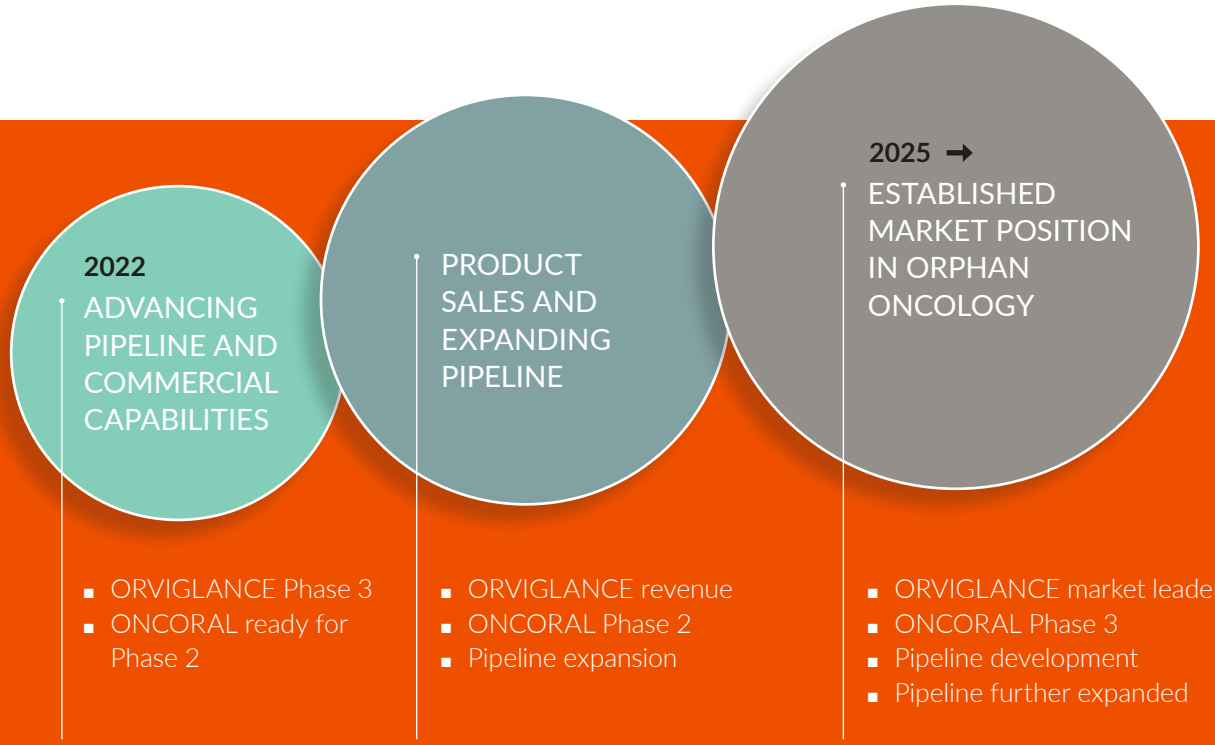
## OUR VISION

To be a leader in identifying, developing and commercializing novel drugs that address unmet needs of people with rare cancer conditions.

## OUR BASE

Our headquarter is in Malmö, Sweden, and our US base is in New Jersey. The shares in the company are listed on NASDAQ Stockholm (ticker: ACE).

## Building the company and building value



# OUR PIPELINE

## **ORVIGLANCE** (Mangoral)
**Diagnostic drug for liver MRI in ongoing Phase 3**

Orviglance is our novel non-gadolinium diagnostic drug (contrast agent) to be used in MRI-scans of the liver. Orviglance is developed to improve the visualization of focal liver lesions (liver metastases and primary liver cancer) in patients with impaired kidneys at risk of severe side-effects from the gadolinium contrast agents currently on the market. Orviglance characteristics:

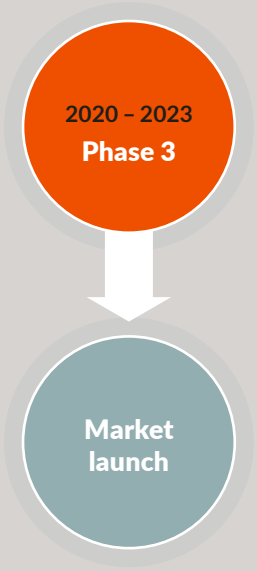
- Manganese-based diagnostic drug with Orphan Drug Designation (FDA)
- The only late-stage gadolinium-free agent
- $500-600 million annual addressable market

## **ONCORAL**
**Tablet chemotherapy ready for Phase 2**

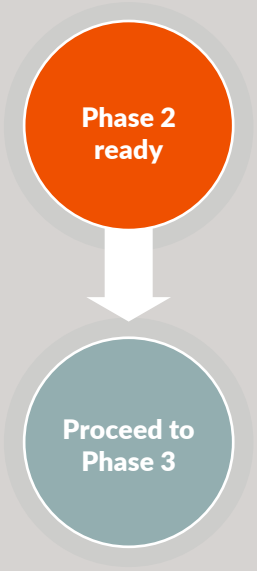
Oncoral is our novel oral chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral characteristics:

- Oral daily dosing of irinotecan chemotherapy
- Potential for better efficacy and safety by frequent low dosing
- Ready for Phase 2 in gastric cancer; potential to expand into other cancer forms

**Expected timelines**




**Orviglance®**
**Visualization of focal liver lesions**
(liver metastases, primary liver cancer)




**Oncoral**
**Gastric cancer treatment**
and expansion potential to other cancer forms

# ORVIGLANCE

Liver MRI contrast agent in the final clinical Phase

## Detecting liver metastases early is essential for survival

Ascelia Pharma's lead drug candidate, Orviglance, is a contrast agent used in Magnetic Resonance Imaging (MRI) to improve the visualization of focal liver lesions (liver metastases and primary tumors). The liver is the second most common organ for metastasis after the lymph nodes. Detecting liver metastases at an early stage is crucial for determining the right treatment method and the patient's chances of survival. Studies show that the five-year survival rate can increase from 6% to 46% if liver metastases can be removed surgically. An accurate MR scan using contrast agents is therefore critical to evaluate the possibility for surgical resection, but also for monitoring of treatment effect and surveillance for recurrence of the disease.

## How Orviglance works

Orviglance is an orally administrated contrast agent developed for use with MRI of the liver. It is based on the chemical element manganese, which is a natural trace element in the body. Orviglance also contains L-Alanine and Vitamin D3 to enhance the function of manganese as a contrast agent. After having been absorbed from the small intestine, the manganese is transported to the liver where it is taken up by and retained in the normal liver cells. The high manganese uptake causes the normal liver tissue to appear bright on MR images. Metastases and tumor cells do not take up manganese to the same extent as normal liver tissue and therefore appear dark on MR images. With Orviglance, liver metastases are consequently easier to identify due to this contrast effect.

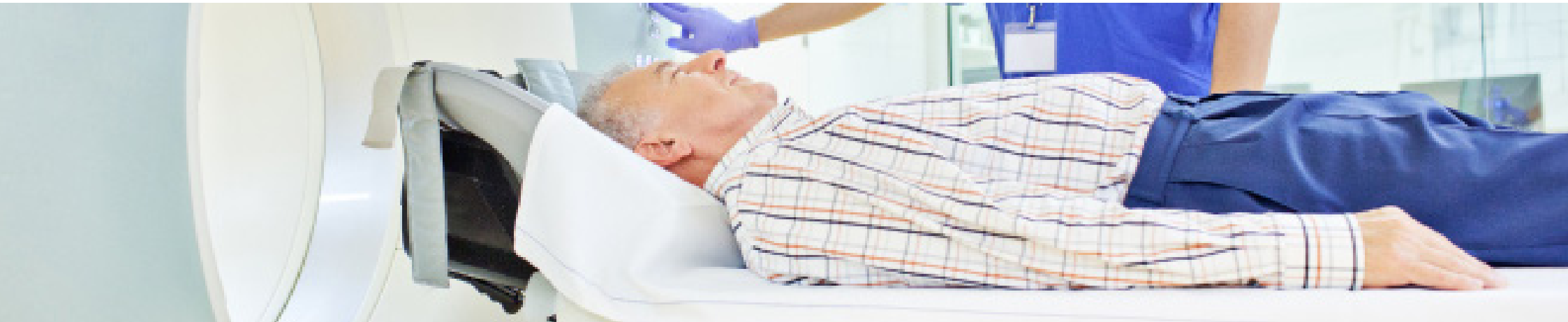
## Latest development

A new analysis of existing phase 2 data, using the same image reading methodology as in the SPARKLE study, demonstrated a strong and statistically significant effect of two to three times the effect level previously expected in SPARKLE. In December, Ascelia Pharma decided and announced the change of patient enrollment target of SPARKLE to 80 patients, after having discussed the possibility to complete SPARKLE with a smaller sample size than initially planned with the US Food and Drug Administration (FDA).

At the end of January it was communicated that 71 patients had completed the SPARKLE study.

In November 2022, the result of the Food Effect Study was presented at the Radiological Society of North America's (RSNA) annual conference.

The study shows that intake of a light meal within 30 minutes prior to Orviglance administration provides similar MRI enhancement of the liver compared to a fasting condition imaging procedure.



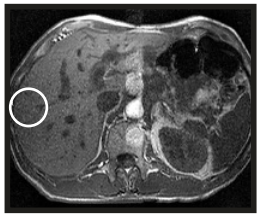
# Patients referred for liver MRI scan

## TODAY

NORMAL KIDNEY
**Gadolinium imaging drug**

POOR KIDNEY FUNCTION
**All gadolinium contrast agents have regulatory Black Box warnings**

**MRI scan <u>without</u> contrast agent: No liver metastasis visible**

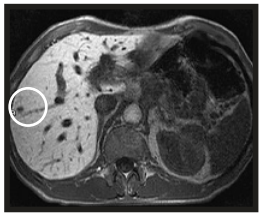


## TOMORROW

NORMAL KIDNEY
**Gadolinium imaging drug**

POOR KIDNEY FUNCTION
**ORVIGLANCE imaging drug**

**MRI scan <u>with</u> Orviglance: Liver metastasis becomes visible**



**Orviglance aims** to be the standard liver MRI contrast agent in patients with severely impaired kidney function

## Addressable market of $500-600 million

The target group for Orviglance is patients with severely impaired kidney function. This patient group is at risk of serious, and potentially fatal, side effects from using the currently available contrast agents. These contrast agents, which all are based on the heavy-metal gadolinium, carry Black Box warnings for patients with severely reduced kidney function.

The clinical trials completed to date show that Orviglance has a potential to improve the diagnostic performance of MRI and offers a significantly better alternative than unenhanced MRI (i.e., MRI without contrast agent).

Consequently, Orviglance fills a significant unmet medical need to improve the diagnosis, and subsequently, the treatment of liver metastases and primary liver cancer.

The immediate addressable market for Orviglance is estimated at $500-600 million yearly and Orviglance is expected to be the only gadolinium-free product on the market for this patient segment.

## Orviglance has Orphan Drug Designation

Orviglance has received Orphan Drug Designation from the FDA. One major advantage of orphan drug status is, among other things, that orphan drugs can obtain longer market exclusivity after market approval.

# ONGOING PHASE 3 STUDY (SPARKLE)

The ongoing pivotal Phase 3 study (SPARKLE) is a global multicentre study in up to 80 patients with suspected or known focal liver lesions and severely impaired kidney function. The objective is to demonstrate an improved visualization of liver lesions compared to MRI without contrast, unenhanced MRI. The primary endpoint of the SPARKLE study is similar to what was studies in the phase 1 and 2 studies. The strong results in the Phase 1and Phase 2 studies, both in terms of safety and efficacy, provide a solid foundation for the ongoing Phase 3 program.

## Orviglance's clinical Phase 3 study

| | |
|---|---|
| **NUMBER OF PATIENTS** | **Global ongoing study of 80 patients** |
| **PRIMARY ENDPOINT** | **Lesion visualisation**<br>• Lesions border delineation (border sharpness of lesions)<br>• Conspicuity (lesion contrast compared to liver background) |
| **COMPARATOR** | **Unenhanced MRI + Orviglance MRI vs. Unenhanced MRI** |
| **EVALUATION** | **Centralised evaluation by 3 radiologists** |
| **RANDOMISATION** | **None – each patient at his/her own control** |
| **FOLLOW-UP** | **Less than a week** |

**Strong support to Phase 3 endpoints from completed studies**

The completed Phase 1 and Phase 2 studies have shown strong efficacy results regarding the endpoints that will be evaluated in the Phase 3 study. The completed studies, involving 178 persons in total[1], have showed a highly significant improvement compared to unenhanced MRI in:

- Delineation: p-value <0.0001
- Conspicuity: p-value <0.0001

Results from both variables underpin that Orviglance significantly improves MRI performance.

[1] The above mentioned results stem from of a blinded-read study, which comprised all imaging data including Phase 1 and Phase 2 data. The blinded-read results have been presented at major radiology conferences

# ADDRESSABLE MARKET OF $500-600 MILLION

### $500-600M annual addresable market in US, EU and Japan

**Market estimate based on:**

- Patients with primary liver cancer or liver metastases and severe kidney impairment (~4%)
- Actual imaging procedures (real-world data)[1]
- Payer and expert input (+75 stakeholders)[2]

**Upsides**

- Other markets, e.g., China
- Annual growth of 4-5%


### Value maximizing go-to-market

| | | |
|---|---|---|
| **US** | **Ascelia Pharma to drive commercialization** | |
| **EU** | **Ascelia Pharma global synergies** | **Commercial partner** |
| **Japan** | | **Commercial partner** |
| **Other** | | **Commercial partner** |

### Strong footprint in the US

1. **SPARKLE Phase 3 Study** at leading US sites
2. **Hepatic Impairment Study** at Texas liver institute
3. **Ascelia Pharma Inc.** Office in New Jersey
4. **Manufacturing** at Cambrex (partner), NJ
5. **Imaging experts** RadMD, NY

### Building an Ascelia Pharma US team

| | |
|---|---|
| **US team** | **Around 40 FTEs at launch** |
| **Clinics/ Hospitals** | **Around 400 clinics and hospitals serve 75% of the target patient population[1]** |

*Sources:*
*1: Ascelia Pharma market research with Decision Resources Group, 2020*
*2: Ascelia Pharma market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020*

# ONCORAL – IRINOTECAN CHEMOTHERAPY AS TABLET

Oncoral is a novel daily irinotecan chemotherapy in development. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily irinotecan tablet with the potential to offer better efficacy with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital.

## Proven anti-cancer effect

The active pharmaceutical ingredient (API) in Oncoral is irinotecan, which has an established and proven effect in killing cancer cells. Irinotecan is so-called antineoplastic agent that after metabolic activation inhibits the enzyme topoisomerase 1, thereby inducing cancer cell death via the prevention of their DNA replication. Irinotecan is converted by carboxylesterases, primarily in the liver, to the active metabolite SN-38 which is 100–1,000 more potent than irinotecan in killing tumor cells.

## Potential to be the first oral irinotecan

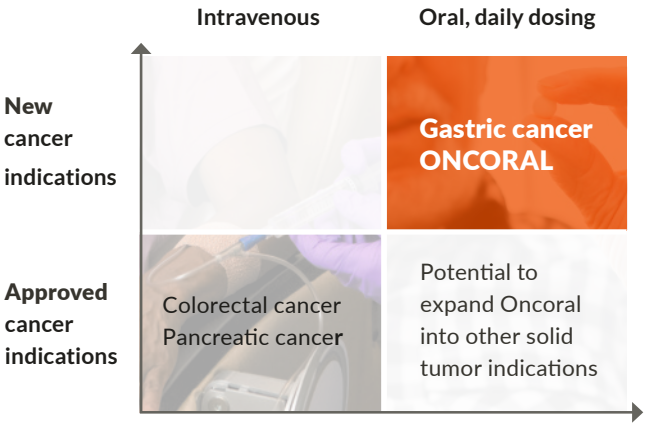
Oncoral is a new patented oral tablet formulation of irinotecan, which enables a reliable release and efficient absorption of irinotecan from the gastro-intestinal tract after oral administration.

Oncoral has the potential to be combined with other chemotherapies and targeted cancer drugs and enable an all-oral chemotherapy combination for treatment of different types of solid tumors.

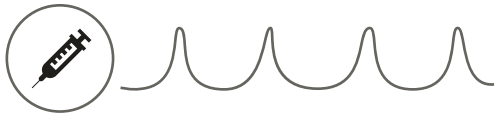
## Latest development

We remain committed to start a Phase 2 study of Oncoral. However, as our clinical development team is fully focused on the completion of SPARKLE, the start of patient enrolment in the study will commence when we are able to do this without impacting SPARKLE.

## Oncoral - a novel formulation of irinotecan




## **TODAY** – Intravenous bolus infusions



**Infrequent high-dose IV irinotecan**

- Gastrointestinal and haematological side effects
- Side-effects: 30% severe or life-threatening (grade 3 or 4)

## **TOMORROW** – Oncoral oral daily dosing

**Potential – Frequent low-dose irinotecan**

- Improved efficacy driven by pharmacokinetic/dynamic profile
- Improved tolerability due to lower peak exposure with less severe side effects and manageable toxicity with flexible dosing

# ONCORAL PHASE 2 STUDY DESIGN

Following an initial dose-finding part, the planned Phase 2 study will be a randomized placebo controlled multicenter study to demonstrate clinical proof of concept in metastatic gastric cancer in combination with LONSURF (tablets with trifluridine and tipiracil). The study is anticipated to inform on doses for further development in the gastric cancer indication, which is a rare form of cancer in USA and Europe, and therefore potentially eligible for Orphan Drug Designation. There is potential for subsequent label expansion into other solid tumor indications where irinotecan has a well-established anticancer effect.

## Phase 2 study design (an all-oral combination study)

| | |
|---|---|
| **TYPE OF STUDY** | Randomized controlled, multicentre, multinational study: Oncoral + LONSURF vs. LONSURF |
| **ENDPOINTS** | **Primary:** Progression Free Survival<br>**Secondary:** Objective Response Rate, PK, Safety and Overall Survival data in a follow up analysis |
| **NUMBER OF PATIENTS** | **Approximately 100 patients** |

# FINANCIAL OVERVIEW: Q4-2022 (OCT–DEC 2022)

## EARNINGS AND PROFITABILITY

### Net sales and other operating income

The Group's net sales in Q4 amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognize revenue before products have been launched on the market. Other operating income totalled SEK 80 thousand (SEK 123 thousand). The income refers to exchange rate gains.

### Research and development costs (R&D)

R&D costs for the Group in Q4 were SEK 43.7 million (SEK 27.9 million). The cost increase of SEK 10.5 million underlines an overall higher activity level in Ascelia Pharma in the current period vis-à-vis corresponding period last year. This was driven by costs related to Orviglance Phase 3 clinical study.

### Commercial preparation costs

During Q4, costs related to commercial preparations for Orviglance amounted to SEK 3.8 million (SEK 6.1 million). This reflects further investments in market launch preparations.

### Administration costs

Administration costs for the Group in Q4 amounted to SEK 4.8 million (SEK 5.3 million). The cost decrease in the current quarter compared with Q4-2021 primarily reflects a decrease in recognized costs for employee incentive programs.

### Operating results (EBIT)

The operating result in Q4 amounted to SEK -52.2 million (SEK -39.2 million). The increased loss reflects the overall higher level of R&D activities in 2022.

### Net Profit/Loss for the period

The Group's net loss in Q4 amounted to SEK -53.4 million (SEK -35.1 million). In the current quarter, net financial cost of SEK 1.7 million was recognized due to weakening of USD against SEK, which translated into a decrease in the value of bank deposits (a significant part of bank deposit is held in USD to match upcoming cash outflow in this currency). The net loss corresponds to a loss per share, before and after dilution, of SEK -1.53 (SEK -1.01).

## CASH FLOW

Cash flow from operating activities before changes in working capital in Q4 amounted to SEK -43.4 million (SEK -35.5 million). The increased outflow reflects the higher level of R&D activities in current quarter. Changes in working capital in the current quarter totalled an inflow of SEK 14.7 million (inflow of SEK 3.3 million). The inflow in the current quarter reflects the increase in accounts payable. Cash flow from investing activities in Q4 totalled to SEK 0 (SEK 0). Cash flow from financing activities amounted to an outflow of SEK -0.2 million (outflow of SEK -0.3 million), which mainly reflects amortization of lease liabilities.

## FINANCIAL POSITION

On the closing date, equity amounted to SEK 180.9 million, compared with SEK 307.8 million per 31 December 2021. The decrease since 31 December 2021 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 149.6 million, compared to SEK 261.6 million per 31 December 2021.The decrease since 31 December 2021 reflects the net loss incurred.

| Financials key ratios for the Group | Q4 (October-December) | |
|---|---|---|
| | 2022 | 2021 |
| Operating result (SEK 000') | -52,167 | -39,160 |
| Net result (SEK 000') | -53,382 | -35,073 |
| Earnings per share (SEK) | -1.53 | -1.01 |
| Weighted avg. number of shares | 34,871,177 | 34,576,448 |
| R&D costs/operating costs (%) | 84% | 71% |
| Cash flow used in operating activities (SEK 000') | -28,714 | -32,246 |
| Equity (SEK 000') | 180,859 | 307,834 |
| Liquid assets incl. marketable securities (SEK 000') | 149,555 | 261,599 |

# FINANCIAL OVERVIEW: FY-2022 (JAN–DEC 2022)

## EARNINGS AND PROFITABILITY

### Net sales and other operating income

The Group's net sales in FY-2022 amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognize revenue before products have been launched on the market. Other operating income totalled SEK 827 thousand (SEK 317 thousand). The income refers to exchange rate gains.

### Research and development costs (R&D)

R&D costs for the Group in FY-2022 were SEK 118.1 million (SEK 107.6 million). The cost increase of SEK 10.5 million reflects the increased patient recruitment compared to last year.

### Commercial preparation costs

During FY-2022, costs related to commercial preparations for Orviglance amounted to SEK 14.9 million (SEK 13.2 million). The cost increase compared with FY-2021 reflects a step-up in market launch preparations.

### Administration costs

Administration costs for the Group in FY-2022 amounted to SEK 14.6 million (SEK 17.1 million). The cost decrease primarily reflects a decrease in recognized costs for employee incentive programs.

### Operating results (EBIT)

The operating result in FY-2022 amounted to SEK -147.0 million (SEK -137.9 million. The increased loss primarily reflects the higher level of R&D costs related to increased patient recruitment compared to FY-2021.

### Net Profit/Loss for the period

The Group's net loss in FY-2022 amounted to SEK -131.2 million (SEK -125.9 million). In the current period, net financial income of SEK 13.3 million was recognized due to primarily strengthening of USD against SEK, which translated into an increase in the value of bank deposits (a significant part of bank deposit is held in USD to match upcoming cash outflow in this currency). The net loss corresponds to a loss per share, before and after dilution, of SEK -3.77 (SEK -3.82).

## CASH FLOW

Cash flow from operating activities before changes in working capital in FY-2022 amounted to SEK -139.9 million (SEK -130.0 million). The increased outflow y/y primarily reflects the higher level of R&D activity in the current period. Changes in working capital for the period totalled an inflow of SEK 14.7 million (inflow of SEK 13.5 million). The inflow in the current period primarily reflects the increase in accounts payable. Cash flow from investing activities in FY-2022 totalled an outflow of SEK -65 thousand (SEK -38 thousand), which reflects a value loss indivestment of a leasing car. Cash flow from financing activities amounted to an outflow of SEK -1.1 million (inflow of SEK 184.9 million), which mainly reflects amortization of lease liabilities.

## FINANCIAL POSITION

On the closing date, equity amounted to SEK 180.9 million, compared with SEK 307.8 million per 31 December 2021. The decrease since 31 December 2021 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 149.6 million, compared to SEK 261.6 million per 31 December 2021. The decrease since 31 December 2021 reflects the net loss incurred.

| Financials key ratios for the Group | FY (January-December) | |
|---|---|---|
| | 2022 | 2021 |
| Operating result (SEK 000') | -147,007 | -137,948 |
| Net result (SEK 000') | -131,223 | -125,903 |
| Earnings per share (SEK) | -3.77 | -3.82 |
| Weighted avg. number of shares | 34,798,504 | 32,959,110 |
| R&D costs/operating costs (%) | 80% | 78% |
| Cash flow used in operating activities (SEK 000') | -125,263 | -116,559 |
| Equity (SEK 000') | 180,859 | 307,834 |
| Liquid assets incl. marketable securities (SEK 000') | 149,555 | 261,599 |

# Other information

## Incentive programs

Ascelia Pharma has one outstanding employee option program as well as share saving programs. If the terms of the option program are met at the time for utilization, the management team has the right to purchase shares at a pre-determined price. For the share-saving program, employees are entitled to receive matching and performance shares according to terms of the program.

The Group recognizes share-based remuneration, which personnel may receive. A personnel cost is recognized, together with a corresponding increase in equity, distributed over the vesting period. Social security costs are revalued at fair value. Further information about the incentive programs can be found in the Annual Report 2021 on pages 67-68.

In case all outstanding incentive programs per 31 December 2022 (incl. a new share-saving program approved by the AGM in May 2022) are exercised in full, a total of 1.2 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 3.4% of Ascelia Pharma's share capital after full dilution (calculated on the number of common shares that will be added upon full exercise of all incentive programs).

## Information about risks and uncertainties for the Group and the parent company

Ascelia Pharma's activities and markets are exposed to a number of risks and uncertainties which impact, or could impact, the company's business, financial position and result. The risks and uncertainties, which Ascelia Pharma considers to have the largest impact on its results are clinical drug development, regulatory conditions, commercialization and licensing, intellectual property rights and other forms of protection, financing conditions, macroeconomic conditions including impact from pandemics, geopolitical effects, inflation and foreign exchange exposure.

The Group's overall strategy for risk management is to limit undesirable impact on its result and financial position, to the extent it is possible. The Group's risks and uncertainties are described in more detail in the Annual Report 2021 on pages 34-36.

## Impact of the Ukraine crisis

Ascelia Pharma decided in March 2022 to suspend all clinical activities, including patient recruitment, in Russia. Moving forward, we don't see any direct impact.

## Significant events after the end of the reporting period

On 27 January 2022 it was announced that 71 patients have completed the SPARKLE study.

## Auditor's review

This interim report has not been reviewed by the company's auditor.

## Annual General Meeting (AGM) 2023

The AGM of Ascelia Pharma AB (publ) will be held on 4 May, 2023. Shareholders wishing to have a matter discussed at the AGM should send their suggestion by e-mail to:
despina.georgiadou@ascelia.com
or by mail to:
ASCELIA PHARMA AB
Hyllie Boulevard 34
SE-215 32 Malmö

Suggestions to the AGM must reach the Board of Directors at least seven weeks prior to the meeting (17 March) or in good time for the matter, if necessary, to be included in the notice to the AGM.

## Dividend

In accordance with Ascelia Pharma's dividend policy, no dividend is proposed and available financial resources is reinvested in the business to finance the company's long-term strategy. The Board of Directors' intention is not to propose a dividend to shareholders before the company is able to generate a longterm sustainable profitability and a long-term sustainable positive cash flow.

This interim report has been prepared in both Swedish and English versions. In the event of any differences between the translations and the Swedish original, the Swedish version shall prevail.

**Magnus Corfitzen**
CEO

Malmö, 10 February 2023
Ascelia Pharma AB (publ)

# Consolidated Income Statement

| | Q4 (Oct-Dec) | | Full Year (Jan-Dec) | |
|---|---|---|---|---|
| SEK in thousands (unless otherwise stated)* | 2022 | 2021 | 2022 | 2021 |
| Net sales | – | – | – | – |
| **Gross profit/loss** | **–** | **–** | **–** | **–** |
| Administrative costs | -4,760 | -5,328 | -14,628 | -17,122 |
| Research and development costs | -43,674 | -27,900 | -118,113 | -107,574 |
| Commercial preparation costs | -3,780 | -6,055 | -14,929 | -13,201 |
| Other operating income | 80 | 123 | 827 | 317 |
| Other operating costs | -33 | – | -163 | -368 |
| **Operating result** | **-52,167** | **39,160** | **-147,007** | **-137,948** |
| Finance income | 2,824 | 3,051 | 17,816 | 10,439 |
| Finance costs | -3,896 | -24 | -3,965 | -2,014 |
| **Net financial items** | **-1,072** | **3,027** | **13,851** | **8,425** |
| **Loss before tax** | **-53,239** | **-36,133** | **-133,155** | **-129,523** |
| Tax | -143 | 1,060 | 1,933 | 3,620 |
| **Loss for the period** | **-53,382** | **-35,073** | **-131,223** | **-125,903** |
| Attributable to: | | | | |
| Owners of the Parent Company | -53,382 | -35,073 | -131,223 | -125,903 |
| Non-controlling interest | – | – | – | – |
| Earnings per share | | | | |
| Before and after dilution (SEK) | -1.53 | -1.01 | -3.77 | -3.82 |

# Consolidated Statement of Comprehensive Income

| | Q4 (Oct-Dec) | | Full Year (Jan-Dec) | |
|---|---|---|---|---|
| *SEK in thousands (unless otherwise stated)** | 2022 | 2021 | 2022 | 2021 |
| **Profit/loss for the period** | **-53,382** | **-35,073** | **-131,223** | **-125,903** |
| **Other comprehensive income** | | | | |
| Currency translation of subsidiaries** | 594 | 66 | 718 | 135 |
| **Other comprehensive income for the period** | **594** | **66** | **718** | **135** |
| **Total comprehensive income for the period** | **-52,788** | **-35,007** | **-130,505** | **-125,768** |

* Some figures are rounded, so amounts might not always appear to match when added up.

** Will be classified to profit and loss when specific conditions are met

# Consolidated Balance Sheet

| *SEK in thousands** | 31 Dec 2022 | 31 Dec 2021 |
|---|---|---|
| **ASSETS** | | |
| **Non-current assets** | | |
| Intangible assets | 57,074 | 57,063 |
| Tangible assets - Equipment | 163 | 238 |
| Right-of-use assets | 462 | 1,581 |
| **Total non-current assets** | **57,700** | **58,882** |
| **Current assets** | | |
| Advance payments to suppliers | 5,359 | 6,175 |
| **Current receivables** | | |
| Income tax receivables | 2,785 | 4,395 |
| Receivables from shareholders | – | – |
| Other receivables | 1,745 | 1,165 |
| Prepaid expenses and accrued income | 1,426 | 1,277 |
| Cash and bank balances | 149,555 | 261,599 |
| **Total current assets** | **160,869** | **274,611** |
| **Total assets** | **218,569** | **333,493** |
| **EQUITY** | | |
| Share capital | 34,871 | 34,576 |
| Other paid-in capital | 678,747 | 678,831 |
| Reserve of exchange differences on translation | 718 | 135 |
| Loss brought forward (incl. net profit/loss for the period) | -533,478 | -405,708 |
| **Equity attributable to Parent Company shareholders** | **180,859** | **307,834** |
| **Total equity** | **180,859** | **307,834** |
| **LIABILITIES** | | |
| **Long-term liabilities** | | |
| Leasing | 193 | 553 |
| **Total long-term liabilities** | **193** | **553** |
| **Current liabilities** | | |
| Accounts payable | 15,881 | 6,147 |
| Tax payable | – | 5 |
| Other liabilities | 1,688 | 1,509 |
| Current lease liabilities | 291 | 1,102 |
| Accrued expenses and deferred income | 19,657 | 16,343 |
| **Total current liabilities** | **37,518** | **25,106** |
| **Total liabilities** | **37,711** | **25,659** |
| **Total equity and liabilities** | **218,569** | **333,493** |

* Some figures are rounded, so amounts might not always appear to match when added up.

# Consolidated Statements of Changes in Equity

| | Full Year (Jan-Dec) | |
|---|---|---|
| *SEK in thousands** | **2022** | **2021** |
| **Equity at start of the period** | **307,834** | **236,056** |
| **Comprehensive income** | | |
| Profit/loss for the period | -131,223 | -125,903 |
| Other comprehensive income | 718 | 135 |
| **Total comprehensive income** | **-130,505** | **-125,768** |
| **Transactions with shareholders** | | |
| New issue of C-shares | 295 | 398 |
| Repurchase of own shares C-shares | -295 | -398 |
| New issue of common shares | – | 200,000 |
| Issuance expenses | -84 | -13,271 |
| Redemption of warrants | – | 3,853 |
| Share based remuneration to employees | 3,612 | 6,964 |
| **Total transactions with shareholders** | **3,529** | **197,546** |
| **Equity at end of the period** | **180,859** | **307,834** |

* Some figures are rounded, so amounts might not always appear to match when added up.

# Consolidated Cash Flow Statement

| | Q4 (Oct-Dec) | | Full Year (Jan-Dec) | |
|---|---|---|---|---|
| *SEK in thousands** | **2022** | **2021** | **2022** | **2021** |
| **Operating activities** | | | | |
| Operating result | -52,167 | -39,160 | -147,007 | -137,948 |
| Expensed share based remuneration | 3,494 | 1,790 | 1,627 | 5,919 |
| Adjustment for items not included in cash flow | 238 | 321 | 1,091 | 1,045 |
| Interest received | 630 | 10 | 635 | 10 |
| Interest paid | -10 | -19 | -48 | -77 |
| Income tax paid/received | 4,416 | 1,559 | 3,772 | 1,020 |
| **Cash flow from operating activities before changes in working capital** | **-43,397** | **-35,499** | **-139,930** | **-130,031** |
| **Cash flow from changes in working capital** | | | | |
| Increase (-)/Decrease (+) of advance payments | -219 | 1,240 | 850 | 2,110 |
| Increase (-)/Decrease (+) of operating receivables | 625 | 81 | -1,362 | -900 |
| Increase (+)/Decrease (-) of accounts payable | 12,045 | -2,119 | 9,722 | 2,258 |
| Increase (+)/Decrease (-) of other liabilities | 2,232 | 4,051 | 5,456 | 10,004 |
| Change in working capital | 14,683 | 3,253 | 14,667 | 13,472 |
| **Cash flow used in operating activities** | **-28,714** | **-32,246** | **-125,263** | **-116,559** |
| **Investing activities** | | | | |
| Investment in equipment | – | – | – | -38 |
| Divestment of right-of-use assets | – | – | -65 | – |
| **Cash flow from investing activities** | **–** | **–** | **-65** | **-38** |
| **Financing activities** | | | | |
| Issuance proceeds | – | – | – | 200,000 |
| Issuance costs | – | – | -84 | -13,271 |
| Redemption of warrants net | – | – | – | -914 |
| Amortisation of loan (leasing) | -239 | -273 | -1,016 | -944 |
| **Cash flow from financing activities** | **-239** | **-273** | **-1,100** | **184,871** |
| **Cash flow for the period** | **-28,954** | **-32,519** | **-126,428** | **68,274** |
| Cash flow for the period | -28,954 | -32,519 | -126,428 | 68,274 |
| Cash and cash equivalents at start of period | 179,811 | 291,029 | 261,599 | 184,686 |
| Exchange rate differences in cash and cash equivalents | -1,302 | 3,089 | 14,384 | 8,639 |
| **Cash and cash equivalents at end of period** | **149,555** | **261,599** | **149,555** | **261,599** |

* Some figures are rounded, so amounts might not always appear to match when added up.

# Parent Company – Income Statement

| | Q4 (Oct-Dec) | | Full Year (Jan-Dec) | |
|---|---|---|---|---|
| *SEK in thousands** | **2022** | **2021** | **2022** | **2021** |
| Net sales | 92 | 1,197 | 1,142 | 5,495 |
| **Gross profit/loss** | **92** | **1,197** | **1,142** | **5,495** |
| Administrative costs | -4,730 | -5,189 | -14,441 | -16,901 |
| Research and development costs | -43,809 | -23,819 | -108,077 | -94,306 |
| Commercial preparation costs | -3,814 | -6,061 | -14,963 | -13,223 |
| Other operating income | 67 | 105 | 124 | 241 |
| Other operating costs | – | – | -131 | -344 |
| **Operating result** | **-52,194** | **-33,767** | **-136,346** | **-119,038** |
| Finance income | 2,791 | 2,731 | 16,721 | 9,830 |
| Finance costs | -3,315 | -4 | -3,384 | -1,940 |
| Result from other long-term receivables | 451 | 679 | 1,639 | 1,860 |
| **Net financial costs** | **-73** | **3,406** | **14,976** | **9,750** |
| Loss before tax | -52,268 | -30,361 | -121,371 | -109,288 |
| Group contribution | – | – | – | – |
| Tax | – | – | – | – |
| **Loss for the period** | **-52,268** | **-30,361** | **-121,371** | **-109,288** |

# Parent Company – Statement of Comprehensive Income

| | Q4 (Oct-Dec) | | Full Year (Jan-Dec) | |
|---|---|---|---|---|
| *SEK in thousands** | **2022** | **2021** | **2022** | **2021** |
| **Loss for the period** | **-52,268** | **-30,361** | **-121,371** | **-109,288** |
| Other comprehensive income | – | – | – | – |
| **Other comprehensive income for the period** | **–** | **–** | **–** | **–** |
| **Total comprehensive income for the period** | **-52,268** | **-30,361** | **-121,371** | **-109,288** |

* Some figures are rounded, so amounts might not always appear to match when added up.

# Parent Company – Balance Sheet

| *SEK in thousands** | 31 Dec 2022 | 31 Dec 2021 |
|---|---|---|
| **ASSETS** | | |
| **Non-current assets** | | |
| Tangible assets | | |
| Equipment | 163 | 238 |
| Financial assets | | |
| Shares in affiliated companies | 58,068 | 58,068 |
| Other long-term receivables from group companies | 38,486 | 36,620 |
| **Total non-current assets** | **96,717** | **94,926** |
| **Current assets** | | |
| Advance payments to suppliers | 5,359 | 5,323 |
| **Current receivables** | | |
| Receivables from group companies | 8,395 | 6,971 |
| Income tax receivables | 756 | 739 |
| Receivables from shareholders | – | – |
| Other receivables | 1,627 | 656 |
| Prepaid expenses and accrued income | 1,349 | 1,183 |
| Cash and bank balances | 137,879 | 246,311 |
| **Total current assets** | **155,365** | **261,183** |
| **Total assets** | **252,082** | **356,109** |
| **EQUITY** | | |
| Restricted equity | | |
| Share capital | 34,871 | 34,576 |
| Non-restricted equity | | |
| Other paid-in capital | 678,747 | 678,831 |
| Loss brought forward | -377,266 | -271,295 |
| Loss for the period | -121,371 | -109,288 |
| **Total equity** | **214,982** | **332,824** |
| **LIABILITIES** | | |
| **Current liabilities** | | |
| Accounts payable | 16,022 | 5,700 |
| Other liabilities | 1,688 | 1,509 |
| Accrued expenses and deferred income | 19,390 | 16,076 |
| **Total current liabilities** | **37,101** | **23,285** |
| **Total equity and liabilities** | **252,082** | **356,109** |

* Some figures are rounded, so amounts might not always appear to match when added up.

# Notes

## General information

This interim report for the Group has been prepared according to IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act (ÅRL). The interim report for the parent company has been prepared according to the Swedish Annual Accounts Act chapter 9, Interim Reporting. For the Group and the parent company, the same accounting principles and basis for calculations have been applied as in the recent Annual Report.

## Fair value of financial instruments

The recognized value for other receivables, cash and cash equivalents, trade payables and other liabilities constitutes a reasonable approximation of fair value.

## Related parties Purchases from related parties

Oncoral Pharma ApS has an agreement with Solural Pharma ApS according to which, Solural Pharma ApS provides development and manufacturing of clinical study material. The owners of Solural Pharma ApS are the founders of Oncoral Pharma ApS and are, after the sale of Oncoral Pharma ApS to Ascelia Pharma AB in 2017, shareholders in Ascelia Pharma AB. Per 31 December 2022, the owners of Solural ApS collectively owned 1.85% of the shares in Ascelia Pharma AB. In addition to payment for services performed, Solural Pharma ApS has the right to receive a bonus of maximum SEK 10 million if commercialization occurs through a sale or a outlicensing and SEK 12 million if commercialization is carried out by Oncoral Pharma ApS or Ascelia Pharma AB itself.

Regardless the commercialization method, Oncoral Pharma ApS has the right to, at any time, finally settle Solural Pharma ApS right for remuneration by payment of SEK 10 million. In FY-2022, services for a value of around SEK 793 thousand were acquired from Solural Pharma ApS.

## Use of non-international financial reporting standards (IFRS) performance measures

Reference is made in this interim report to alternative performance measures that are not defined according to IFRS. Ascelia Pharma considers these performance measures to be an important complement since they enable a better evaluation of the company´s economic trends. The company believes that these alternative performance measures give a better understanding of the company´s financial development and that such key performance measures contain additional information to the investors to those performance measures already defined by IFRS. Furthermore, the key performance measures are widely used by the management in order to assess the financial development of the company. These financial key performance measures should not be viewed in isolation or be considered to substitute the key performance measures prepared by IFRS.

Furthermore, such key performance measures should not be compared to other key performance measures with similar names used by other companies. This is due to the fact that the above-mentioned key performance measures are not always defined identically by other companies. These alternative performance measures are described below.

## Important estimations and judgements

### *Valuation of intangible assets*

The recognized research and development project in progress is subject for management's impairment test. The most critical assumption, subject to evaluation by management, is whether the recognized intangible asset will generate future economic benefits that at a minimum correspond to the intangible asset's carrying amount. Management's assessment is that the expected future cash flows will be sufficient to cover the intangible asset's carrying amount and accordingly no impairment loss has been recognized.

### *Capitalization of development expenses*

In FY-2022, the criteria for classifying R&D costs as an asset according to IAS 38 has not been met (capitalization of development expenses is normally done in connection with final regulatory approval). Hence, all R&D costs related to the development of the product candidates have been expensed.

### *Share-based incentive programs*

#### *Employee option programs*

Ascelia Pharma has implemented two employee option programs with individual terms and conditions. The parameter, which have the largest impact on the value of the options, is the publicly traded share price.

In 2021, one program reached its exercise period and all options related to this program, 481,573 in total, were exercised into common shares.

For the outstanding option program, a gain of SEK 1.0 million including social security charges was recognized in FY-2022. The gain primarily reflects the decline in Ascelia Pharma's share price during the period resulting in a lower liability for social security charges.

#### *Share saving programs*

Ascelia Pharma has implemented four long-term incentive programs for employees in the form of performance-based share saving programs. The parameter, which have the largest impact on the value of the programs, is the publicly traded share price.

The total recognized costs for the share saving programs including social security charges in FY-2022 were SEK 2.6 million.

# Notes

## Definitions of alternative performance measures

| Alternative performance measures | Definition | Aim |
|---|---|---|
| **Operating results (TSEK)** | Profit before financial items and tax. | The performance measure shows the company´s operational performance. |
| **Research and development costs/Operating costs (%)** | The research and development expenses in relation to total operating costs (consisting of the sum of administrative expenses, R&D, costs for commercial preparations and other operating expenses). | The performance measure is useful in order to understand how much of the operating costs that are related to research- and development expenses. |

## Reconciliation table for alternative performance measures for the Group

| | Q4 (Oct-Dec) | | Full Year (Jan-Dec) | |
|---|---|---|---|---|
| *SEK in thousands** | 2022 | 2021 | 2022 | 2021 |
| R&D costs | -43,674 | -27,900 | -118,113 | -107,574 |
| Administration costs | -4,760 | -5,328 | -14,628 | -17,122 |
| Commercial preparation costs | -3,780 | -6,055 | -14,929 | -13,201 |
| Other operating costs | -33 | – | -163 | -368 |
| **Total operating costs** | **-52,246** | **-39,283** | **-147,834** | **-138,265** |
| **R&D costs/Operating costs (%)** | **84%** | **71%** | **80%** | **78%** |

## Financial calendar

| | |
|---|---|
| Annual General Meeting 2022: | 4 May 2023 |
| Interim report Q1 2023 (Jan-Mar): | 11 May 2023 |
| Half-year report H1 2023 (Jan-Jun): | 18 August 2023 |
| Interim report 9M 2023 (Jan-Sep): | 8 November 2023 |
| Full-year report 2023 (Jan-Dec): | 9 February 2024 |

## Contact

Magnus Corfitzen, CEO
moc@ascelia.com | +46 735 179 118

Déspina Georgiadou Hedin, CFO
despina.georgiadou@ascelia.com | +46 765 697 873

Mikael Widell, Head of IR & Communications
mw@ascelia.com | +46 703 119 960

ASCELIA PHARMA

**ASCELIA PHARMA AB** (publ)
Hyllie Boulevard 34
SE-215 32 Malmö, Sweden

ascelia.com